DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

St. Jude Medical
c/o Mr. William McKelvey
Senior Regulatory Affairs Specialist
177 East County Road B, East
St. Paul, MN 55117

Re: K083835
Attune™ Adjustable Flexible Annuloplasty Ring Model AFR
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: December 22, 2008
Received: December 23, 2008

Dear Mr. McKelvey:

This letter corrects our substantially equivalent letter of January 23, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Volkmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

U.S. Food and Drug Administration – Center for Devices and Radiological Health

510(k) Number (if known):K083835

Device Name: Attune™ Adjustable Flexible Annuloplasty Ring

Indications For Use

The Attune™ Adjustable Flexible Annuloplasty Ring is indicated for use in the repair of a mitral or tricuspid valve that is diseased or damaged due to acquired or congenital valvular disease. It is the responsibility of the surgeon to determine that the valve is repairable. The decision to undertake annuloplasty can be made only after visual analysis of the valve pathology. Only surgeons who have received appropriate training should perform valve repair using the Attune™ Adjustable Flexible Annuloplasty Ring

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083835

510(K) SUMMARY

(as required by 21 CFR 807.92)

A. Submitters Information

Submitter's Name and Address:

St. Jude Medical
177 County Road B, East
St. Paul, MN 55117

Contact Name

William McKelvey, RAC
Sr. Regulatory Affairs Specialist
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Submission Prepared

December 22, 2008

Amendment January 16, 2009

B. Device Information

Proprietary Name:

Attune™ Adjustable Flexible Annuloplasty Ring model AFR-(size)

Common or Usual Name:

Adjustable Flexible Annuloplasty ring, Mitral/Tricuspid Repair Ring

Classification:

Class II per 21 CFR 870.3800, Annuloplasty rings

Predicate Device:

Tailor Annuloplasty Ring Model TARP-(size) – 510 (k) K014161

Device Description:

The Attune™ Adjustable Flexible Annuloplasty Ring is a fully flexible ring fabricated with a medical grade silicone rubber core surrounded by polyester fabric and containing a suture that will allow adjustment after implantation.

Intended Use:

The Attune™ Adjustable Flexible Annuloplasty Ring is intended for mitral or tricuspid heart valve repair using conventional open heart, minimally invasive or robotic surgical techniques.

C. Comparison of Required Technological Characteristics

St. Jude Medical considers the Attune™ Adjustable Flexible Annuloplasty Ring to be substantially equivalent in technological characteristics (e.g. design and materials) and intended use to the predicate device. The table below is a comparison of the equivalency characteristics between the Attune™ Adjustable Flexible Annuloplasty Ring and the predicate device.

Characteristic	Equivalency
a. Product Labeling	Substantially Equivalent
b. Indications for Use	Identical
c. Physical Characteristics	Substantially Equivalent
d. Anatomical Sites	Identical
e. Target Population	Identical
f. Performance Testing	Substantially Equivalent
g. Safety Characteristics	Substantially Equivalent

D. Summary of Non-Clinical Tests

The following performance characteristics were evaluated;

- Ring Tensile Strength
- Suture Pullout Test
- Ring Adjustability Test
- Security of Final Adjustment Knot Test
- MR Safety Evaluation
- Manufacturing Process validation
- Biological Evaluation
- Sterilization Parameter Evaluation

Conclusion

St Jude Medical has demonstrated that the Attune™ Adjustable Flexible Annuloplasty Ring is safe and effective for the intended use. The Attune™ Adjustable Flexible Annuloplasty Ring is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.